DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-044

Hoffman-La Roche Inc.
Attention : Duane Voss
Program Director, DRA
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Voss:

Please refer to your supplemental new drug application dated November 5, 2007, received November 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an extension of the expiration dating from 5 years to 7 years for Tamiflu® Capsules, 30 mg, 45 mg, and 75 mg, along with revised regulatory specifications for individual and total impurities, for dissolution, and for appearance.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Valerie Jimenez, MS, Senior Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Eric P. Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eric Duffy

12/3/2007 03:32:55 PM